

# EXHIBIT 5

Roy Benaroch, MD  
5161 Stratham Drive  
Dunwoody, GA 30338

Kevin Moore, Attorney at Law  
6111 Peachtree Dunwoody Road, NE  
Building C, Suite 201

RE: Goodrich v Fisher Price

September 26, 2017

Dear Mr. Moore,

At your request I've reviewed the medical records re: your client in the above case. You've asked me to provide my take on this matter. As you know, I am a practicing general pediatrician with 20 years' experience. I am also an Adjunct Assistant Professor of Pediatrics with Emory University, with responsibility for teaching medical students, physician assistant students, and pediatric residents. I have also published two books, three video lecture series, and hundreds of articles on child health care issues on dozens of venues. I have taken both a personal and professional interest in baby and child safety, and I am very familiar with both American and international recommendations for a safe infant sleep environment.

Let me address first the general issues regarding safe infant sleep and how those apply to the Fisher Price Rock 'n Play device that was involved with your case. After that, I'll address what I have gleaned from this baby's medical records.

Excluding prematurity, birth defects, and their complications, the leading cause of death of infants in the United States is Sudden Infant Death Syndrome (SIDS). SIDS is considered the cause of the death of an infant that cannot be explained after a thorough case investigation (including an on-scene investigation, autopsy, and review of the infant's medical history.) SIDS is considered a subtype of a broader category called Sudden Unexpected Infant Death (SUID), which includes known causes of death like suffocation, asphyxia, entrapment, infections, or previously undiagnosed heart conditions. The distinction between SIDS and SUID is not always straightforward, even after a very thorough evaluation. However, the well-established risk factors for both of these conditions

have considerable overlap, and the “safe sleep guidelines” are an evidence-based, rigorously researched effort to minimize the preventable risk of death of any infant from any cause.

Regarding the device under consideration, the Fisher Price Rock ‘n Play **SLEEPER** (emphasis mine), this is clearly being sold as and marketed as a sleeping device – a product whose intended use is as a place for infants to sleep. As I will show, it is not fit for its intended use as a sleeper, and is therefore a defective product. The danger of using the device is severe: it may result in the death of a baby from positional asphyxia. The manufacturer does not warn parents against allowing their babies to sleep in the device; in fact, they encourage the use of the device in a way that is inherently dangerous. The danger could easily have been avoided with a minor design change (keeping the bottom of the device flat rather than inclined.) The danger of the device, unfortunately, may not be obvious to parents, who may be unfamiliar with the scientific literature and guidelines that show that a flat, 100%-supine, non-inclined sleep position is safest for babies.

A 2008 case series by Cote (cite <https://www.ncbi.nlm.nih.gov/pubmed/17641002>) reviewed reports of 17 deaths of otherwise healthy infants while in inclined car seats. This was followed by a clinical study comparing the oxygenation of healthy, term babies while flat versus while inclined (cite <http://pediatrics.aappublications.org/content/124/3/e396.short> ). This study, titled “A comparison of respiratory patterns in healthy term infants placed in car safety seats and beds,” showed that healthy, term babies were at risk for desaturation (dropping their blood oxygen) when placed on an inclined surface.

Studies like these informed the definitive guideline for a safe sleeping environment, published in October 2011 by the American Academy of Pediatrics (AAP), titled *SIDS and Other Sleep-Related Infant Deaths: Expansion of recommendations for a Safe Infant Sleeping Environment* (cite <http://pediatrics.aappublications.org/content/pediatrics/early/2011/10/12/peds.2011-2284.full.pdf>.) There is also an accompanying technical report which includes further details on the rationale and research behind the AAP’s recommendations (reference on request). These recommendations have been supported by the CDC (<https://www.cdc.gov/sids/Parents-Caregivers.htm>), the American Academy of Family Physicians (<http://www.aafp.org/afp/2012/0501/p918.html>), numerous state health agencies (<https://archive.cdph.ca.gov/programs/SIDS/Pages/2.1SafeSleepEnvironment.aspx>), and the Consumer Product Safety Commission (<https://www.cpsc.gov/content/a-safe-sleep-for-all-babies-cpsc-and-child-safety-partners-launch-national-education>). Very similar recommendations have been made by just about every other country in the world. These recommendations were updated by the AAP in November, 2016 – and none of the newer recommendations contradict any of the following points (the 2016 guideline is here: [https://www.cpsc.gov/s3fs-public/AAP\\_Sleep%20Death%20Policy%20Statement%202016.pdf](https://www.cpsc.gov/s3fs-public/AAP_Sleep%20Death%20Policy%20Statement%202016.pdf)). In brief, these safe sleep guidelines are well-established as the standard, safest way to provide a safe sleep environment for a baby.



I'm going to highlight the individual recommendations from the AAP, using verbiage from their 2011 report, and contrast that with the design and marketing of the Fisher-Price Rock 'n Play product. The numbers below refer exactly to the numbered items in the AAP report, followed by relevant quotes from that document (in bold) and my comments.

**1. "To reduce the risk of SIDS, infants should be placed for sleep in a supine position (wholly on the back) for every sleep by every caregiver until 1 year of life."**

The Rock 'n Play Sleeper does not keep a baby wholly on the back, but rather in an inclined position.

**2. Use a firm sleep surface—A firm crib mattress, covered by a fitted sheet, is the recommended sleeping surface to reduce the risk of SIDS and suffocation.**

The Rock 'n Play Sleeper is not a firm crib mattress, but rather a sling-like apparatus that is curved rather than straight.

**2e. Sitting devices, such as car safety seats, strollers, swings, infant carriers, and infant slings, are not recommended for routine sleep in the hospital or at home.**

Though this sentence doesn't specifically mention the Rock 'n Play Sleeper, it is inclined and shaped like the devices in this category, and is therefore not recommended for sleep.

**2e. If an infant falls asleep in a sitting device, he or she should be removed from the product and moved to a crib or other appropriate flat surface as soon as is practical.**

Babies should not be left to sleep in a device like the Rock 'n Play Sleeper.

**16. Media and manufacturers should follow safe-sleep guidelines in their messaging and advertising.**

The packaging and advertising material for the Rock 'n Play Sleeper regularly portrays infants sleeping alone in the product, not under direct supervision. In fact, the first sentence describing the product on the Fisher-Price web site (accessed today) is "The inclined seat helps baby sleep all night long." This product is being sold and marketed for baby sleep, and is being sold and marketed as an inclined device. This directly contradicts the AAP's safe sleep guideline.

There are multiple, additive, and well-established risk factors for SIDS and SUID. For the purposes of this discussion, we will concentrate on those that put a baby at increased risk while sleeping in the Fisher-Price Rock 'n Play Sleeper. The primary mechanisms by which this device can contribute to a baby's death are by (1) holding the baby in a semi-upright, or inclined position – which can allow a baby's head to tip forward; and (2) holding the baby in a sling or banana-like shape, which can also contribute to the potential mal-positioning

of the head and neck. A baby's head is relatively large, compared to an adult's; babies also have limited neck strength, and a small trachea (upper airway.) If the head pitches forward towards the chest in a "flexed" position, that can crimp shut the upper airway. Lacking good neck strength and motor control, a baby may not be able to reposition the head to re-open the airway. With a closed airway, death by suffocation will quickly ensue. Note that a baby with a closed airway will be unable to cry out or vocalize—lacking breath, the baby cannot "call for help" in any way. The "sling like", snug shape may further limit a baby's ability to struggle to open the airway. Without breath, a baby will quickly lose tone and consciousness, turn blue, and die.

I have reviewed the medical records from Baby Goodrich's visit first to Hughes Spalding Children's Hospital then to Henrietta Eggleston Hospital. As you know, the baby was brought to Hughes Spalding first with a chief complaint of "Turning Blue". Notes indicated that the baby was found blue and limp by the Grandmother, who picked up and stimulated the baby, who then resumed breathing after about 20 seconds. The notes explicitly state that there had been no vomiting nor spit up, and that the baby had otherwise been well. A number of tests were done, summarized here with the final results: blood and urine tests for infection were negative; an EKG and later echocardiogram had only subtle findings that were interpreted as non-diagnostic and non-contributory by a consulting cardiologist; and continued monitoring during an overnight hospitalization revealed no further concerning events.

During the hospitalization, the "Apnea Service" was consulted. Their "differential diagnosis" – the list of potential causes for the baby's event – started with their #1 consideration, "upper airway obstruction by head being flexed". This is exactly the mechanism of airway compromise that can occur with sleep in the Rock 'n Play. Their other considerations were #2, "GERD", referring to "gastroesophageal reflux disease". They considered this a "weak history", and this possibility was not supported by the history (there had been no spit up or vomit), and not supported by the baby's subsequent course (there were no further events.) The child was not treated for GERD, and this possibility was disregarded as too unlikely. The third possibility, "urosepsis", was proven false by the medical evaluation, and was never treated.

After hospital discharge, the baby was sent home with an "apnea monitor", which recorded no concerning events. This supports the diagnosis of apnea caused by upper airway obstruction from neck flexion, since it stopped happening when the family stopped sleeping the baby in the Rock 'n Play.

In summary, the Rock 'n Play Sleeper is not a safe sleeping device. It places babies at risk for upper airway compromise and death. Based on my review of the medical records, my familiarity with safe sleep guidelines, and my training and experience including 20 years as a pediatrician, I conclude that sleeping while positioned in the Rock 'n Play was the cause of Baby Goodrich's apneic episode.

Yours truly,

A handwritten signature in black ink, appearing to read 'Roy Benaroch', with a stylized flourish at the end.

Roy Benaroch, MD